U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

B/O Form PTO-1390 **Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under *35 USC 371***		*Attorney's Docket Number* REF/SAWATZKI/409
		U.S. Application Number (if known) 09/581520
International Application Number PCT/EP98/08409	*International Filing Date* 22 December 1998	*Priority Date Claimed* 13 December 1997
Title of Invention FAT BLEND		
Applicant(s) for DO/EO/US SAWATZKI et al.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items under *35 USC 371*:

1. ☒ This is a **FIRST** submission of items concerning a filing under *35 USC 371*.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under *35 USC 371*.
3. ☒ This express request to begin national examination procedures *(35 USC 371(f))* at any time rather than delay examination until the expiration of the applicable time limit set in *35 USC 371(b)* and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed *35 USC 371(c)(2)*.
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English *(35 USC 371(c)(2))*.
7. ☒ Amendments to the claims of the International Application under PCT Article 19 *(35 USC 371(c)(3))*
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 *(35 USC 371(c)(3))*.
9. ☐ An oath or declaration of the inventor(s) *(35 USC 371(c)(4))*. (☐ Executed ☐ Unexecuted)
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 *(35 USC 371(c)(5))*.

Items 11 to 16 below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under *37 CFR 1.97* and *1.98*.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with *37 CFR 3.28* and *3.31* is included.
13. ☒ A **FIRST** preliminary amendment.
    ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ Other items or information:

Application Number (if Known)	International Application Number	Attorney's Docket Number
09/581520	PCT/EP98/08409	REFSAWATZKI/409

	Calculations	PTO USE ONLY
17. The following fees are submitted: **Basic National Fee *(37 CFR 1.492(a)(1)-(5))*:** ☒ Search report has been prepared by the EPO or JPO . . . . . $840.00 ☐ International Preliminary Examination Fee paid to USPTO *(37 CFR 1.482)* . . . . . $670.00 ☐ No International Preliminary Examination Fee paid to USPTO *(37 CFR 1.482)* but International Search Fee paid to USPTO *(37 CFR 1.445(a)(2))* . . . . . $760.00 ☐ Neither International Preliminary Examination Fee *(37 CFR 1.482)* nor International Search Fee *(37 CFR 1.445(a)(2))* paid to USPTO . . . . . $970.00 ☐ International Preliminary Examination Fee paid to USPTO *(37 CFR 1.482)* and all claims satisfied provisions of PCT Article 33(1)-(4) $96.00	$840.00	
ENTER APPROPRIATE BASIC FEE AMOUNT	**$ 840.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date *(37 CFR 1.492(e))*.		

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	20 -20 =	0	× $18.00	$ 0.00	
Independent Claims	1 -3 =	0	× $78.00	$ 0.00	
Multiple Dependent Claims (if applicable)			+ $260.00		
TOTAL OF ABOVE CALCULATIONS				**$ 0.00**	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity Statements must also be filed (Note *37 CFR 1.9, 1.27, 1.28)*					
SUBTOTAL				**$ 840.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date *(37 CFR 1.492(f))*.					
TOTAL NATIONAL FEE					
Fee for recording the enclosed assignment *(37 CFR 1.21(h))*. The assignment must be accompanied by an appropriate cover sheet *(37 CFR 3.28, 3.31)*. **$40.00** per property.					
TOTAL FEES ENCLOSED				**$ 840.00**	
Amount to be:				Refunded:	
				Charged:	

a. ☒ A check in the amount of **$840.00** to cover the fees is enclosed.

b. ☐ Please charge my **Deposit Account Number 02-0200** in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to **Deposit Account Number 02-0200**. A duplicate copy of this sheet is enclosed.

Note: Where an appropriate time limit under *37 CFR 1.494* or *1.495* has not been met, a petition to revive *(37 CFR 1.137(a) or (b))* must be filed and granted to restore the application to pending status.

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DATE: June 23, 2000

Respectfully submitted,

Richard E Fichter

Richard E. Fichter
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SAWATZKI et al.

U.S. National Phase of PCT/EP98/08409

Entry papers filed herewith June 23, 2000

For: FAT BLEND

Attention: PCT OFFICE

PRELIMINARY AMENDMENT
AND INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The present application is the U.S. national phase of international application number PCT/EP98/08409.

Please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please add the attached ABSTRACT OF THE DISCLOSURE to the application.

An English translation is herewith submitted with the application.

IN THE CLAIMS:

Claim 4, line 1, please cancel "one of the foregoing Claims" and insert - -claim 1- -.

Claim 5, line 1, please cancel "one of the foregoing Claims" and insert - -claim 1- -.

Claim 7, line 1, please cancel "one of the foregoing Claims" and insert - -claim 1- -.

Claim 8, line 1, please cancel "one of the foregoing Claims" and insert - -claim 1- -.

Claim 9, lines 1 and 2, please cancel "one of the foregoing Claims 1 to 8" and insert - -claim 1- -.

Claim 13, line 1, please cancel "one of Claims 8 to 12" and insert - -claim 8- -.

Please cancel claim 15 without prejudice or disclaimer and add the following new claims to the application.

- -16. Fat blend according to claim 2, characterised in that it contains arachidonic acid and that the quotient of the sum of the gamma-linolenic acid plus stearidonic acid plus eicosapentaenoic acid to the arachidonic acid is at least 10:1.

17. Fat blend according to claim 3, characterised in that it contains arachidonic acid and that the quotient of the sum of the gamma-linolenic acid plus stearidonic acid plus eicosapentaenoic acid to the arachidonic acid is at least 10:1.

18. Fat blend according to claim 2, characterised in that the phospholipids comprise 1 to 10 wt. % of the total lipids.

19. Fat blend according to claim 3, characterised in that the phospholipids comprise 1 to 10 wt. % of the total lipids.

20. Fat blend according to claim 4, characterised in that the phospholipids comprise 1 to 10 wt. % of the total lipids.

21. Fat blend according to claim 2, characterised in that the sum of the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid present in the fat blend in the form of phospholipids comprises up to 120 mg/g total fatty acids.- -

REMARKS

Applicants have amended the claims in order to delete the improper use claim 15 and to reduce the initial filing fee by deleting the multiple dependent claims from the application. Applicants have reintroduced some of the canceled subject matter by adding new claims 16-21 and retain the right to reintroduce any further subject matter canceled by the present Amendment at any time during the prosecution of this application or any further application claiming benefit of this application.

Also, an Abstract of the Disclosure has been added to the application.

Applicants are submitting herewith a copy of the Search Report which issued on International Application No. PCT/EP98/08409, of which the present application is the U.S. national phase. All of the publications cited in the International Search Report are listed on the attached Form PTO-1449. It is Applicants' understanding that, under the procedures of the PCT, copies of the cited publications will have been supplied to the U.S. Patent Office by the International Bureau. However, the Examiner is invited to contact the undersigned attorney if additional copies are necessary or would facilitate examination of the present application.

Otherwise, the Examiner is respectfully requested to return an initialed and dated copy of the attached Form PTO-1449 to confirm that all publications listed thereon have been considered and made officially of record in the file of this application.

Applicants understand that, under the procedures of the PCT, a copy of the priority document (DE 197 57 414.9, filed 23 December 1997) will have been supplied to the U.S. Patent Office pursuant to Rule 17 of the PCT Regulations. It is therefore respectfully requested that the first Official Action in the present application contain an indication that the appropriate priority document is in the file of this application.

In view of the above amendments, an early action on the application is now in order and is most respectfully requested.

Respectfully submitted,
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PCTPRELI.AMD.wpd

DATE: June 23, 2000

ABSTRACT OF THE DISCLOSURE

The invention relates to an oil, fat and/or lecithin-based fat blend containing polyunsaturated fatty acids. The inventive fat blend is characterised in that the fatty acids gamma-linolenic, stearidonic acid and eicosapentaenoic together make up 10 to 500 mg/g total fatty acids. The gamma-linolenic and eicosapentaenoic acids each represent 20 to 50 wt. % and the stearidonic acid represents 15 to 50 wt. % of the sum of these three fatty acids. The inventive fat blend can be incorporated into a dietetic or a pharmaceutical product, especially a dietetic food, and can be used especially for administering to patients suffering from chronic/inflammatory diseases, disorders of the lipid metabolism, a weakened immune function and/or a restricted lipolytic capacity of the gastrointestinal tract.

Fat Blend

DESCRIPTION

The invention concerns a fat blend based on oils, fats and/or lecithins with polyunsaturated fatty acids, a dietetic or pharmaceutical composition containing this fat blend and the use of this fat blend or this dietetic or pharmaceutical composition.

It is well-known that the body is capable of endogenously synthesising certain saturated and monounsaturated fatty acids including stearic acid (C18-0) and oleic acid (C18-1w9). However the body is not capable of endogenously synthesising the polyunsaturated fatty acids linoleic acid (18-2w6) and alpha-linolenic acid (C18-3w3), necessary for it, so that these fatty acids must be supplied exogenously with the diet and hence are also described as essential fatty acids.

A great variety of longer-chain (C20 and C22) and higher desaturated fatty acids are then synthesised from these essential fatty acids in the human fatty acid metabolism by chain elongation and desaturation. The fatty acids which are derived from linoleic acid (C18-2w6) are referred to as the w6 family, while the w3 family is derived from alpha-linolenic acid. In English, these polyunsaturated fatty acids are also described as polyunsaturated fatty acids or PUFA. For more details of the descriptive code or nomenclature used in the present documents, the reader is referred to in "Lipid Analysis" by William W Christie, Pergamon Press 1973.

The said polyunsaturated fatty acids are structural components of all cell membranes of the body. A few specific fatty acids from the w3 and w6 family are of especial importance since special molecules are synthesised from them, which are collectively described as eicosanoids.

The collective term eicosanoids is now understood to mean an extremely diverse and complex mixture of physiologically highly active, hormone-like compounds, which are involved in a great variety of regulatory processes in the body. The eicosanoids are mainly derived from the w6- and w3-desaturated C20 precursor fatty acids dihomo-gamma-linolenic

acid (DGLA; 20-3w6), arachidonic acid (AA; 20-4w6), eicosatetraenoic acid (20-4w3) and eicosapenta-enoic acid (EPA; 20-5w3).

The biological effects of the eicosanoids formed from the polyunsaturated fatty acids differ enormously, depending on whether the eicosanoids are derived from the w6 or w3 family. In general, anti-inflammatory effects are attributed to the eicosanoids of the w3 series, while the eicosanoids of arachidonic acid from the w6 family have a pro-inflammatory character.

Owing to the dietary practices and types of diet, especially in the Western countries, there is now an increase in the arachidonic acid contents in the membrane lipids of the body's cells and hence increased synthesis of the pro-inflammatory eicosanoids derivable from arachidonic acid.

Now recently, attempts have been made favourably to influence the clinical pictures of various chronic inflammatory diseases and lipid metabolism disorders through the deliberate dietetic intake of specific polyunsaturated fatty acids. Thus for example EP-A 0 756 827 and EP-A 0 764 405 describe the administration of fat blends or fat mixtures based on evening primrose oil and/or fish oil for modulation of the immune system. DE-A 39 24 607 recommends the use of dietetic products based on fish oil for lowering blood pressure in hyperlipidaemias. Further, in EP-A 0 457 950, the use of stearidonic acid in pharmaceutical compositions for the treatment of diseases of inflammatory origin is described.

Also already offered on the market are fat emulsions for enteral feeding, which as essential fatty acids contain gamma-linolenic acid (GLA), eicosapentaenoic acid (EPA) and in some cases also stearidonic acid (SA), which are intended to serve for immunomodulation.

However, in all the products described in the publications cited, and also in the products available on the market, the polyunsaturated fatty acids utilised are present in an unbalanced proportion one to another.

The object of the present invention is to provide an improved fat blend and a dietetic or pharmaceutical composition containing this, with which the fatty acid metabolism and in

particular the eicosanoid metabolism can be optimally influenced, so that by administration of this fat blend or food the symptoms and the clinical problems of patients with various diseases can be significantly improved.

This object is achieved by a fat mixture or a fat blend, respectively, and a dietetic foodstuff containing this fat blend according to the teaching of the claims.

Namely, it has surprisingly been found that the eicosanoid metabolism of arachidonic acid can be effectively and optimally influenced by administration of the polyunsaturated fatty acids gamma-linolenic acid (GLA), eicosapentaenoic acid (EPA) and stearidonic acid (SA) in a specific, balanced proportion one to another. Hence it is claimed that in the fat blend the GLA and the EPA each comprise 20 to 50 wt. % and the SA 15 to 50 wt. % of the sum formed from these three fatty acids. Further, the sum of these fatty acids together comprises 10 to 500 mg per g of total fatty acid (sum of all the fatty acids present).

If the three named fatty acids are administered in the claimed quantity and in the claimed proportions, then the formation of pro-inflammatory eicosanoids of arachidonic acid is negatively influenced. In addition, the physiological equilibrium of the eicosanoids is shifted with the prospect of an anti-inflammatory and lipid-lowering action. Also, by means of the fat blend according to the invention, a development- or illness-related decrease in the lipolytic capacity of the gastrointestinal tract can be stimulated and improved [sic].

Thus, according to the invention a fat blend is provided, which is distinguished by high contents and a specific proportion of certain polyunsaturated fatty acids one to another. This fat blend or a foodstuff containing this can be administered to patients with acute and chronic inflammatory diseases, to patients with autoimmune diseases, to patients with metabolic disorders (hyperlipidaemias), to patients with weakened immune function and to patients with limited lipolytic capacity of the gastrointestinal tract. Further application fields of the subject matters claimed according to the invention are explained in more detail below.

In the fat blend according to the invention, the fatty acids are preferably present in that form in which they are bound in the oil, fat and lecithin raw material utilised, i.e. in particular as

triglycerides and phospholipids. However, these fatty acids can also wholly or in part be present as free fatty acids, as esters, for example simple alkyl esters such as ethyl esters, or in salt form. It is also possible to use transesterified fatty acids. Thus for example the blend according to the invention can be supplemented with such free fatty acids, simple fatty acid esters and fatty acid salts. It is also even comprised according to the invention that the blend according to the invention may consist exclusively of these free fatty acids, simple fatty acid esters and/or fatty acid salts and hence terminologically would itself also have to be described as a fatty acid blend.

The fat blend according to the invention advantageously contains different oils, fats and/or lecithins. Thus for example the fat blend can contain different oils, fats and lecithins such as have no or only low contents of polyunsaturated fatty acids. In order then to incorpor-ate the latter fatty acids in the fat blend, these oils, fats and/or lecithins are mixed with such that do contain the polyunsaturated fatty acids.

The oils, fats and or lecithins can be common ones, for example animal and plant ones. However, oils, fats and lecithins of microbial and/or synthetic origin and hence also newly developed starting materials can be also be used. Raw materials still to be developed in the future can also be used, since all that matters as regards the starting materials used is that they contain the specified fatty acids in the stated amounts and proportions.

According to a preferred embodiment, the fatty acids GLA, SA and EPA together comprise 10 to 100 mg per g of the total fatty acids present; in addition, the GLA and the EPA each comprise 35 to 45 wt. % and the SA 15 to 25 wt. % of the sum of these three fatty acids. If in the context of the present documents a range is mentioned, then all intermediate values falling within this range are disclosed. Thus the expression 10 to 100 mg or 10 to 500 mg is only a shortened expression for all values lying between these, in particular all whole number values, for example 10, 11, 12, 13, 15, . . . 30, 31, 32, 33 . . . 65, 66, 67, 68 . . . 85, . . . 104, 105, 106, . . . 150, 151, 152, . . . 187, 188, 189, 190, . . . 215, 216, 217, . . . 241, 242, 243, . . . 268, 269, 270, . . . 280, . . . 290, . . . 300, 301, 302, 303, 304 . . . , 310 . . . , 320 . . . , 330 . . . , 340 . . . , 350 . . . , 360, 361 . . . , 370 . . . , 380 . . . , 390. . . , 400 . . . , 410 . . . , 415, 416, 417 . . . , 420 . . . , 430 . . . , 440 . . . , 450 . . . , 460 . . . , 470 . . . , 480 . . . , 490, 491 . . ., 495, 496

. . . . The same applies for the weight percentage ranges from 15 to 50 wt. %, 35 to 45 wt. % and 15 to 25 wt. %. Thereby, at least all whole number values lying between these are disclosed, for example 15, 18, 21, 24, 27, 28, 31, 33, 37, 39, 40, 42, 44, 47 and 49. In addition, all smaller ranges covered by the larger ranges are also covered as well.

The aforesaid also applies with respect to the fat contents claimed in the present documents in the form of energy % and for the claimed weight percentage data for the lecithins. Here also, all whole number values between the limit values of these ranges are disclosed.

According to a preferred embodiment, the fat blend also contains arachidonic acid (AA). Here the quotient of the sum of GLA + SA + EPA to the AA is at least 10:1.

According to a further preferred embodiment, the lecithin content is up to 40 wt. % of the total lipids (= sum of the oils, fats and lecithins), preferably 1 to 10 wt. %.

According to a further preferred embodiment, the sum of the fatty acids GLA, SA and EPA present in the fat blend in the form of phospholipids comprises up to 120 mg/g of the total fatty acids, preferably 0.05 to 50 mg per g of the total fatty acids. These fatty acids present in the form of phospholipids can thus for example comprise 0.05, 0.1, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 mg per g total fatty acids. Again, in this case also, all ranges lying between the limit values are disclosed.

As already stated, the fat blend according to the invention can be prepared by mixing animal, plant, microbial and/or synthetic oils, fats and/or lecithins together in defined quantity proportions.

As plant oils, for example "conventional" oils from mono- and dicotyledonous plants (such as for example coconut oil, palm nut oil, palm oil, soya oil, sunflower oil, rape oil) can be used. For deliberate increasing of the gamma-linolenic (GLA) and stearidonic acid (SA) content, "special" plant oils such as borage oil, evening primrose oil, echiuma oil, trichodesma oil, and also the seed oils of other species, e.g. from the Boraginaceae, Scrophulariaceae, Onagraceae and Saxifragaceae families, can be used. In addition, for example GLA- and SA-rich

concentrates produced in chemical or enzymatic ways and also those obtained from the said sources by chromatographic separation can be used. As animal fats and oils, for example, egg oils, fish oils and oils from marine mammals, and also for example eicosapentaenoic acid-rich or stearidonic acid-rich concentrates produced in chemical or enzymatic ways and also those obtained from these raw materials by chromatographic separation can be used. Further, gamma-linolenic, stearidonic and eicosapentaenoic acid-containing oils and fats of microbial origin or appropriate algal and fungal oils and concentrates derivable from these can be used.

Further, specific GLA-, SA- and EPA-containing lecithins can be used in the fat blend according to the invention; among these may be named lecithins from egg-yolk, preferably those which as a result of modified feeding display a w3-PUFA-accentuated fatty acid spectrum, and in addition other natural w3-PUFA-containing lecithins, for example from fish, marine mammals or from microorganisms, and also lecithins whose content of GLA, SA and EPA, preferably in the sn-2 position on the glycerine skeleton, has been enriched in chemical or enzymatic ways. Further, medium-chain triglycerides (MCT) can be used in the claimed fat blend. The expressions "fats, oils and lecithins" used here mean technological starting materials. On the other hand, terms such as phospholipids and triglycerides refer to the chemical species. Thus it is quite possible for an oil also to contain phospholipids (often also described as lecithins) and for a lecithin also to contain triglycerides. As oils here, in particular commercially available oils which are deslimed or delecithinised are used. However, the untreated raw oils can also be used as required.

For stabilisation of the claimed, highly unsaturated fat blend against oxidative spoilage, natural and synthetic antioxidants (such as ascorbyl palmitate, tocopherols, etc.) known to the skilled person can be used. Further, the claimed contents of lecithins of animal, plant and/or microbial origin in the fat blend contribute to the oxidation stability thereof.

The following table 1 shows the raw materials or fats, oils and lecithins from which various preferred embodiments of the fat blend according to the invention were prepared by mixing. The likewise following table 2 shows the resulting fatty acid composition of a few of the

practical examples set out in table 1. The expression "blend" here is a synonym for the expression "mixture".

Table 1: Composition of Example Fat Blends

(Data in Wt.%)

Raw Materials	Blend A	Blend B	Blend C	Blend D	Blend E	Blend F
MCT fat	30.0	30.0	30.0	--	30.0	30.0
Palm oil	26.0	16.5	20.0	26.0	26.0	26.0
Soya oil	16.5	11.5	8.0	16.5	17.5	13.5
Coconut oil				30.0	--	
Borage oil	8.0	10.0	12.0	--	--	--
Echiuma oil	11.0	13.0	18.0	19.0	19.0	19.0
Fish oil A	--	16.0	--	--	--	--
Fish oil B	6.5	--	10.0	6.5	6.5	6.5
Egg lipids/egg lecithins	2.0	--	2.0	2.0	1.0	5.0
Fish lecithin		3				

Table 2. Fatty acid composition of the fat blends shown in table 1

(Data in wt. % unless otherwise stated)

Parameter		Blend A	Blend B	Blend C	Blend D	Blend E	Blend F
8-0		17.2	16.5	16.5	2.5	16.5	16.5
10-0		12.0	13.3	13.3	1.9	13.3	13.3
12-0		0.4	0.1	0.1	13.9	0.2	0.2
14-0		0.4	1.4	0.3	5.7	0.4	0.4
16-0		14.1	13.0	11.7	16.6	13.8	14.3
18-0	stearic acid	2.7	2.5	2.6	3.6	2.6	3.2
18-1w9	oleic acid	19.2	15.8	16.8	21.5	19.4	19.6
18-2w6	linoleic acid	17.5	15.2	15.1	15.8	15.6	14.0
18-3w6	gamma-linolenic acid (GLA)	3.1	3.8	4.8	2.4	2.4	2.4
18-3w3	alpha-linolenic acid	4.2	4.5	5.7	6.4	6.5	6.3
18-4w3	stearidonic acid (SA)	1.6	2.1	2.5	2.5	2.5	2.5
20-3w6	di-homo-gamma-linolenic acid (DGLA)	0.02	0.04	0.05	0.02	0.02	0.03
20-4w6	arachidonic acid (AA)	0.2	0.23	0.2	0.2	0.1	0.3
20-5w3	eicosapentaenoic acid (EPA)	3.0	3.2	4.7	3.0	3.0	3.0
22-6w3	docosahexaenoic acid	1.0	2.9	1.5	1.0	0.9	1.2
Ratio of total w6 to w3		2.1:1	1.5:1	1.4:1	1.4:1	1.4:1	1.3:1
Ratio of 18-3w6 + 18-4w3 + 20-5w3 to 20-4w6		38.5:1	39.3:1	51.9:1	39.5:1	79.0:1	26.3:1
ΣA: 18-3w6 + 18-4w3 + 20-5w3		7.7	9.1	11.9	7.9	7.9	7.9
18-3w6 (as % ΣA)		40.3	41.7	39.9	30.4	30.4	30.4
18-4w3 (as % ΣA)		20.8	23.0	21.2	31.7	31.7	31.7
20-5w3 (as % ΣA)		39.0	35.4	38.9	38.0	38.0	38.0

The fat blend according to the invention can also be incorporated according to the state of the technology in a dietetic or pharmaceutical composition. This also includes the use of the fat blend itself or also of components thereof in microencapsulated form. The further components of this foodstuff or dietetic product or pharmaceutical can be also of known and of any desired nature and are matched to the relevant requirements. Preferably this is a fat emulsion, a ready-for-use food, a liquid food, a reconstituted powder food or a reconstitutable powder food. These foods serve in particular for parenteral, enteral and/or oral administration. However, they can also be a food-bar or a spreadable paste.

The liquid foods and reconstitutable powder foods according to the invention serve in particular for parenteral, enteral and/or oral feeding, and preferably have a fat content which contributes 10 to 55 energy %; the energy density is preferably 0.5 to 3.0 kcal/ml. Further, the fat content especially preferably comprises 25 to 40 energy %, while the energy density is especially preferably 1.1-1.4 kcal/ml.

The dietetic foodstuffs according to the invention contain not only a fat mixture or a fat blend of the type described here, but can also contain other products, for example protein of animal and/or plant origin, e.g. milk, whey, peas, wheat and/or soya, in the form of complex and/or hydrolysed protein with or without addition of free amino acids and/or dipeptides as well as carbohydrates (maltodextrins), vitamins, roughage, minerals, trace elements, choline, taurine, carnitine, inositol and nucleotides in different quantity proportions and optionally water. These further components can be mixed with the fat blend as desired.

The following table 3 shows the lipid and fatty acid contents of some fat blends according to the invention, which are incorporated into liquid foods. Table 4 shows the values for the compositions of various liquid foods according to the invention. Table 5 shows examples of formulae for fat emulsions according to the invention.

Table 3: Lipid and fatty acid contents of examples of liquid foods containing a fat blend according to the invention

(Data in mg/1500 ml, unless otherwise stated)

Parameter		Unit	Based on Blend A		Based on Blend C		Based on Blend F	
Total energy		kcal	1875		1875		1875	
Total fat		en.%	25.0	35.0	25.0	35.0	25.0	35.0
		g	52.1	72.9	52.1	72.9	52.1	72.9
Phospholipid content		%	2		2		5	
MCT		%	30.0		30.0		30.0	
LA	18-2w6	mg	9115	12760	7865	11010	7292	10208
GLA	18-3w6	mg	1615	2260	2479	3471	1250	1750
ALA	18-3w3	mg	2188	3063	2964	4149	3281	4594
SA	18-4w3	mg	833	1167	1318	1845	1302	1823
DGLA	20-3w6	mg	10	15	16	22	16	22
AA	20-4w6	mg	104	146	120	168	156	219
EPA	20-5w3	mg	1563	2188	2422	3391	1563	2188
DHA	22-6w3	mg	521	729	755	1057	625	875
Σ18-3w6 + 18-4w3 +20-5w3 (total)		mg	4010	5615	6234	8728	4115	5760

Table 4: Composition of examples of liquid foods according to the invention

(data in each case relates to 100 ml)

		Example 1	Example 2	Example 3
Energy	kcal	125	100	200
Protein	en.%	24	24	24
Protein	g	7.5	6	12
Glutamine (g)	g	1.51	1.2	2.4
Arginine (g)	g	0.87	0.70	1.40
Fat	en.%	30	30	30
Fat	g	4.2	3.3	6.6
Lecithin	g	0.084	0.066	0.132
Carbohydrates	en.%	46	46	46
	g	14.4	11.5	23.0
Roughage	g	0-0.9	0-7.2	0-14.4
Vitamins, minerals and trace elements		fully balanced	fully balanced	fully balanced
Selenium (µg)	µg	2 - 15	2 - 15	2 - 15
Vit.A (mg RE)	mgRE	0.05 - 0.3	0.05 - 0.3	0.05 - 0.3
Vit.C (mg)	mg	4 - 35	4 - 35	4 - 35
Vit.E (mg TE)	mgTE	0.5 - 15	0.5 - 15	0.5 - 15
Beta-carotene (mg)	mg	0 - 1.5	0 - 1.5	0 - 1.5

Other substances:				
Choline	mg	10 - 100	10 - 100	10 - 100
Taurine	mg	0 - 50	0 - 50	0 - 50
Carnitine	mg	0 - 20	0 - 20	0 - 20
Inositol	mg	0 - 30	0 - 30	0 - 30
Water		to 100 ml	to 100 ml	to 100 ml

Table 5:

Practical examples of the fat emulsions claimed

(Data in g / 100 ml)

Content	Content	Components	% Distribution
3.0	6.0	MCT fat	30 %
3.0	6.0	Canola oil	30 %
1.2	2.4	Fish oil B (45/10)	12 %
1.8	3.6	Borage oil	18 %
1.0	2.0	Echiuma oil	10 %
Sum:	Sum:		Sum:
10	20	oils and fats	100 %
1.2	1.2	egg lecithin	
2.25	2.25	glycerol USP	
to 100 ml	to 100 ml	water (for injection)	

The fat blend according to the invention and the dietetic or pharmaceutical composition according to the invention containing this can in particular be used for the treatment of patients with the following disease states:

1. Patients with acute and chronic inflammatory diseases, with autoimmune diseases and with weakened immune function: e.g. patients with Crohn's disease, psoriasis, chronic polyarthritis, rheumatism; patients with neurodegenerative diseases, patients with pulmonary diseases, patients in the postoperative phase, HIV/AIDS patients, tumour patients, patients with cystic fibrosis, septicaemic patients, high risk patients (in danger of infection, for the avoidance/reduction of nosocomial infections), critically ill patients (e.g. polytraumas, post-traumatic, post-aggression metabolism, metabolic stress), in patients with generalised inflammatory syndrome (SIRS: "systemic inflammatory response syndrome"), multiple organ failure and/or for avoidance thereof; in coronary patients after angioplasty or bypass operation (restenosis, graft occlusion) for the support of immunosuppressive therapy in patients after organ transplants and in diabetics.

2. Patients with Lipid Metabolism Disorders:

e.g. patients with cardiovascular diseases, hyperlipidaemias, metabolic syndrome, inter alia.

3. Patients with Limited Lipolytic Capacity of the Gastrointestinal Tract:

e.g. patients with Crohn's disease, ulcerative colitis, genetic (cystic fibrosis, Schwachmann syndrome) development-related (neonates) or acquired exocrine pancreatic insufficiency, with short intestine syndrome or gastrointestinal tract damaged by radiation or cytostatic compositions, after acute or chronic total parenteral feeding and also patients with diseases of the liver and bile ducts (chronic hepatitis, alcohol syndrome, fatty liver).

Patent Claims

1. Fat blend, built up from the components which are selected from the group consisting of oils, fats, lecithins, fatty acids and salts and esters thereof, and containing polyunsaturated fatty acids,
characterised in that the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid together comprise 10 to 500 mg perg total fatty acids and
the gamma-linolenic acid and the eicosapentaenoic acid each comprise 20 to 50 wt. % and the stearidonic acid 15 to 50 wt. % of the sum of these three fatty acids.

2. Fat blend according to Claim 1,
characterised in that the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid together comprise 10 to 100 mg per g total fatty acids and
the gamma-linolenic acid and the eicosapentaenoic acid each comprise 35 to 45 wt. % and the stearidonic acid 15 to 25 wt. % of the sum of these three fatty acids.

3. Fat blend according to Claim 2,
characterised in that the gamma-linolenic acid and the eicosapentaenoic acid each comprise ca. 40 wt. % and the stearidonic acid ca. 20 wt. % of the sum of these three fatty acids.

4. Fat blend according to one of the foregoing Claims,
characterised in that it contains arachidonic acid and that the quotient of the sum of the gamma-linolenic acid plus stearidonic acid plus eicosapentaenoic acid to the arachidonic acid is at least 10:1.

5. Fat blend according to one of the foregoing Claims,
characterised in that the content of phospholipids is up to 40 wt. % of the total lipids (= sum of the oils, fats and lecithins).

6. Fat blend according to Claim 5,
characterised in that the phospholipids comprise 1 to 10 wt. % of the total lipids.

7. Fat blend according to one of the foregoing Claims,
characterised in that the sum of the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid present in the fat blend in the form of phospholipids comprises up to 120 mg/g total fatty acids.

8. Fat blend according to one of the foregoing Claims,
characterised in that the sum of the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid present in the fat blend in the form of phospholipids comprises 0.05 to 50 mg/g total fatty acids.

9. Dietetic or pharmaceutical composition containing a fat blend according to one of the foregoing Claims 1 to 8.

10. Composition according to Claim 9,
characterised in that it is a fat emulsion, a ready-for-use food, a liquid food, a reconstituted or reconstitutable powder food, in particular for parenteral, enteral and/or oral administration, a food strip or a spreadable paste.

11. Composition according to Claim 10 in the form of a liquid food or reconstituted powder food for parenteral, enteral and/or oral feeding,
characterised in that the fat content is 10 to 55 energy % and the energy density is 0.5 to 3.0 kcal/ml.

12. Composition according to Claim 11,
characterised in that the fat content is 25 to 40 energy % and the energy density is 1.1 to 1.4 kcal/ml.

13. Composition according to one of Claims 8 to 12 in the form of a liquid food or reconstituted powder food,
characterised in that the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid together comprise 0.5 to 30 g/1500 ml of the liquid food.

14. Composition according to Claim 13, characterised in that the gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid together comprise 1 to 10 g/1500 ml of the liquid food.

15. Use of a fat blend according to one of Claims 1 to 8 or of a dietetic or pharmaceutical composition according to one of Claims 9 to 14 for parenteral, enteral and/or oral administration to patients with chronic inflammatory diseases, with lipid metabolism disorders, with weakened immune function and/or with limited lipolytic capacity of the gastrointestinal tract.

Summary

A fat blend based on oils, fats and/or lecithins with a content of polyunsaturated fatty acids is provided. This fat blend is distinguished in that the fatty acids gamma-linolenic acid, stearidonic acid and eicosapentaenoic acid together comprise 10 to 500 mg perg total fatty acids and the gamma-linolenic acid and the eicosapentaenoic acid each comprise 20 to 50 wt. % and the stearidonic acid 15 to 50 wt. % of the sum of these three fatty acids. This fat blend can also be incorporated in a dietetic or pharmaceutical composition, in particular a dietetic foodstuff and serves in particular for administration to patients with chronic/inflammatory diseases, with fat metabolism disorders, with weakened immune function and/or with limited lipolytic capacity of the gastrointestinal tract.

NOT-004-030-US

ATTORNEY/DOCKET NO: REF/SAWATZKI/409

DECLARATION FOR PATENT APPLICATION AND APPOINTMENT OF ATTORNEY

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention (Design, if applicable) entitled:
FAT BLEND

the specification of which (check one):

☐ is attached hereto, or ☒ was filed on: 22 December 1998 as PCT International Application Number: PCT/EP98/08409

and (if applicable) was amended on:

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in *Title 37, Code of Federal Regulations, §1.56*. I hereby claim foreign priority benefits under *Title 35, United States Code §119* of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN APPLICATION(S)			PRIORITY CLAIMED	
Number	Country	Day/Month/Year Filed	Yes	No
197 57 414.9	Germany	23 December 1997	X	

☐ Additional Priority Application(s) Listed on Following Page(s)

I HEREBY CLAIM THE BENEFIT UNDER TITLE 35 U.S. CODE §119(E) OF ANY U.S. PROVISIONAL APPLICATIONS LISTED BELOW.	
Application Number	Day/Month/Year Filed

☐ Additional Provisional Application(s) Listed on Following Page(s)

I hereby claim the benefit under *Title 35, United States Code, §120* of any United States application(s) or PCT international application(s) designating The United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of *Title 35, United States Code, §112*, I acknowledge the duty to disclose information which is material to patentability as defined in *Title 37, Code of Federal Regulations, §1.56* which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

Application Number	Filing Date	Status - Patented, Pending or Abandoned

☐ Additional US/PCT Priority Application(s) listed on Following Page(s)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under *section 1001 of title 18 of the United States Code* and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: I (We) hereby appoint as my (our) attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: J. Ernest Kenney, Reg. No. 19,179; Eugene Mar, Reg. No. 25,893; Richard E. Fichter, Reg. No. 26,382; Charles R. Wolfe, Jr., Reg. No. 28,680; Thomas J. Moore, Reg. No. 28,974; Joseph DeBenedictis, Reg. No. 28,502; Benjamin E. Urcia, Reg. No. 33,805; and

I(we) authorize my(our) attorneys to accept and follow instructions from JAEGER und KOSTER regarding any matter related to the preparation, examination, grant and maintenance of this application, any continuation, continuation-in-part or divisional based thereon, and any parent resulting therefrom, until I(we) or my(our) assigns withdraw this authorization in writing.

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☒ *See following page(s) for additional joint inventors.*

(04AUG1998)

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